

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use, Fluzone® High-Dose safely and effectively. See full prescribing information for Fluzone High-Dose.

**Fluzone High-Dose (Influenza Virus Vaccine)  
Suspension for Intramuscular Injection  
2012-2013 Formula  
Initial US Approval: 2009**

**INDICATIONS AND USAGE**

Fluzone High-Dose is indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. (1)  
Fluzone High-Dose is approved for use in persons 65 years of age and older. (1)

Approval of Fluzone High-Dose is based on superior immune response relative to Fluzone. Data demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose are not available.

**DOSAGE AND ADMINISTRATION**

- For intramuscular use only

A single 0.5 mL dose for intramuscular injection in adults 65 years and older (2.1)

**DOSAGE FORMS AND STRENGTHS**

Suspension for injection in prefilled syringe (gray plunger rod), 0.5 mL. (3)

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**CONTRAINDICATIONS**

Severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine. (4)

**WARNINGS AND PRECAUTIONS**

- If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone High-Dose should be based on careful consideration of the potential benefits and risks. (5.1)

**ADVERSE REACTIONS**

- In adults ≥65 years of age, the most common injection-site reaction was pain (>30%); the most common solicited systemic adverse events were headache, myalgia, erythema and malaise (>10%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

**USE IN SPECIFIC POPULATIONS**

Safety and effectiveness of Fluzone High-Dose has not been established in pregnant women. (8.1)

See **17 PATIENT COUNSELING INFORMATION** and FDA – approved patient labeling.

Revised: May 2012

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\*Sections or subsections omitted from the full prescribing information are not listed.

1 **FULL PRESCRIBING INFORMATION:**

2 **1 INDICATIONS AND USAGE**

3 Fluzone® High-Dose is an inactivated influenza virus vaccine indicated for active immunization  
4 against influenza disease caused by influenza virus subtypes A and type B contained in the  
5 vaccine.

6  
7 Fluzone High-Dose is approved for use in persons 65 years of age and older.

8  
9 Approval of Fluzone High-Dose is based on superior immune response relative to Fluzone. Data  
10 demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose relative  
11 to Fluzone are not available.

12  
13 **2 DOSAGE AND ADMINISTRATION**

- 14 • **For intramuscular use only**

15 **2.1 Dose and Schedule**

16 Fluzone High Dose should be administered as a single 0.5 mL injection by the intramuscular route  
17 in adults 65 years and older.

18  
19 **2.2 Administration**

20 Inspect Fluzone High-Dose syringes visually for particulate matter and/or discoloration prior to  
21 administration. If either of these conditions exist, the vaccine should not be administered.

22  
23 Before administering a dose of vaccine, shake the prefilled syringe.

1

2 The preferred site for intramuscular injection is the deltoid muscle. The vaccine should not be  
3 injected into the gluteal area or areas where there may be a major nerve trunk.

4

5 Do not administer this product intravenously or subcutaneously.

6

7 Fluzone High-Dose vaccine should not be combined through reconstitution or mixed with any  
8 other vaccine.

9

### 10 **3 DOSAGE FORMS AND STRENGTHS**

11 Fluzone-High Dose is a suspension for injection.

12

13 Fluzone High-Dose is supplied in prefilled syringes (gray syringe plunger rod), 0.5 mL, for adults  
14 65 years of age and older.

15

### 16 **4 CONTRAINDICATIONS**

17 A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine [see [Description](#)  
18 [\(11\)](#)], including egg protein, or to a previous dose of any influenza vaccine is a contraindication to  
19 administration of Fluzone High-Dose.

20

### 21 **5 WARNINGS AND PRECAUTIONS**

#### 22 **5.1 Guillain-Barré Syndrome**

1 The 1976 swine influenza vaccine was associated with an elevated risk of Guillain-Barré  
2 syndrome (GBS). Evidence for a causal relation of GBS with other influenza vaccines is  
3 inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1  
4 million persons vaccinated (1). If GBS has occurred within 6 weeks of previous influenza  
5 vaccination, the decision to give Fluzone High-Dose should be based on careful consideration of  
6 the potential benefits and risks.

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## 5.2 Preventing and Managing Allergic Reactions

10 Appropriate medical treatment and supervision must be available to manage possible anaphylactic  
11 reactions following administration of the vaccine.

12

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## 5.3 Altered Immunocompetence

14 If Fluzone High-Dose is administered to immunocompromised persons, including those receiving  
15 immunosuppressive therapy, the expected immune response may not be obtained.

16

17

## 5.4 Limitations of Vaccine Effectiveness

18 Vaccination with Fluzone High-Dose may not protect all recipients.

19

# 6 ADVERSE REACTIONS

20

## 6.1 Clinical Trials Experience

1 Because clinical trials are conducted under widely varying conditions, adverse event rates  
2 observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trial  
3 of another vaccine, and may not reflect the rates observed in practice.

4

5 Adults 65 years of age and older were randomized to receive either Fluzone High-Dose or

6 Fluzone (year 2006-2007 formulation) in a multi-center, double-blind trial conducted in the US.

7 The safety analysis set included 2573 Fluzone High-Dose recipients and 1260 Fluzone recipients.

8

9 [Table 1](#) summarizes solicited injection-site reactions and systemic adverse events reported within  
10 7 days post-vaccination via diary cards. Onset was usually within the first 3 days after vaccination  
11 and a majority of the reactions resolved within 3 days. Solicited injection-site reactions and  
12 systemic adverse events were more frequent after vaccination with Fluzone High-Dose compared  
13 to Fluzone.

1 **Table 1: Frequency of Solicited Injection-Site Reactions and Systemic Adverse Events**  
2 **Within 7 Days After Vaccination with Fluzone High-Dose or Fluzone, Adults 65 Years of**  
3 **Age and Older**

	Fluzone High-Dose (N <sup>a</sup> =2569-2572)			Fluzone (N <sup>a</sup> =1258-1260)		
	Any	Moderate <sup>b</sup>	Severe <sup>c</sup>	Any	Moderate <sup>b</sup>	Severe <sup>c</sup>
<b>Injection-Site Pain</b>	35.6	3.7	0.3	24.3	1.7	0.2
<b>Injection-Site Erythema</b>	14.9	1.9	1.8	10.8	0.8	0.6
<b>Injection-Site Swelling</b>	8.9	1.6	1.5	5.8	1.3	0.6
<b>Myalgia</b>	21.4	4.2	1.6	18.3	3.2	0.2
<b>Malaise</b>	18.0	4.7	1.6	14.0	3.7	0.6
<b>Headache</b>	16.8	3.1	1.1	14.4	2.5	0.3
<b>Fever<sup>d</sup></b>	3.6	1.1	0.0	2.3	0.2	0.1

4 <sup>a</sup>N is the number of vaccinated subjects with available data for the events listed.

5 <sup>b</sup>Moderate - Injection-site pain: sufficiently discomforting to interfere with normal behavior or activities; Injection-  
6 site erythema and Injection-site swelling: ≥2.5 cm to <5 cm; Fever: >100.4°F to ≤102.2°F; Myalgia, Malaise, and  
7 Headache: interferes with daily activities

8 <sup>c</sup>Severe - Injection-site pain: incapacitating, unable to perform usual activities; Injection-site erythema and Injection-  
9 site swelling: ≥5 cm; Fever: >102.2°F; Myalgia, Malaise, and Headache: prevents daily activities

10 <sup>d</sup>Fever –Any Fever indicates ≥99.5°F. The percentage of temperature measurements that were taken by oral route or  
11 not recorded were 97.9% and 2.1%, respectively for Fluzone High-Dose; and 98.6% and 1.4%, respectively for  
12 Fluzone

13  
14 Within 6 months post-vaccination, 156 (6.1%) Fluzone High-Dose recipients and 93 (7.4%)  
15 Fluzone recipients experienced a serious adverse event. No deaths were reported within 28 days  
16 post-vaccination. A total of 23 deaths were reported during the period Day 29–180 post-

1 vaccination: 16 (0.6%) among Fluzone High-Dose recipients and 7 (0.6%) among Fluzone  
2 recipients. The majority of these participants had a medical history of cardiac, hepatic, neoplastic,  
3 renal, and/or respiratory diseases. No deaths were considered to be caused by vaccination.

4

## 5 **6.2 Post-Marketing Experience**

6 The following events have been spontaneously reported during the post-approval use of Fluzone  
7 or Fluzone High-Dose. Because these events are reported voluntarily from a population of  
8 uncertain size, it is not always possible to reliably estimate their frequency or establish a causal  
9 relationship to vaccine exposure. Adverse events were included based on one or more of the  
10 following factors: severity, frequency of reporting, or strength of evidence for a causal  
11 relationship to Fluzone or Fluzone High-Dose.

12

13 Events Reported During Post-Approval Use of Fluzone.

- 14 • *Blood and Lymphatic System Disorders*: Thrombocytopenia, lymphadenopathy
- 15 • *Immune System Disorders*: Anaphylaxis, other allergic/hypersensitivity reactions (including  
16 urticaria, angioedema)
- 17 • *Eye disorders*: Ocular hyperemia
- 18 • *Nervous System Disorders*: Guillain-Barré syndrome (GBS), convulsions, febrile  
19 convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy  
20 (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination),  
21 dizziness, paresthesia
- 22 • *Vascular Disorders*: Vasculitis, vasodilatation/flushing

- 1 • *Respiratory, Thoracic and Mediastinal Disorders:* Dyspnea, pharyngitis, rhinitis, cough,  
2 wheezing, throat tightness
- 3 • *Skin and Subcutaneous Tissue Disorders:* Stevens-Johnson syndrome
- 4 • *General Disorders and Administration Site Conditions:* Pruritus, asthenia/fatigue, pain in  
5 extremities, chest pain
- 6 • *Gastrointestinal Disorders:* Vomiting

7

8 Other Events Reported During Post-Approval Use of Fluzone High-Dose.

- 9 • *Gastrointestinal Disorders:* Nausea, diarrhea
- 10 • *General Disorders and Administration Site Conditions:* Chills

11

## 12 **7 DRUG INTERACTIONS**

13 Data evaluating the concomitant administration of Fluzone High-Dose with other vaccines are not  
14 available.

15

## 16 **8 USE IN SPECIFIC POPULATIONS**

17

### 18 **8.1 Pregnancy**

18 Pregnancy Category C: Animal reproduction studies have not been conducted with Fluzone High-  
19 Dose. It is also not known whether Fluzone High-Dose can cause fetal harm when administered to  
20 a pregnant woman or can affect reproduction capacity. Fluzone High-Dose should be given to a  
21 pregnant woman only if clearly needed.

22

23

### 24 **8.4 Pediatric Use**

1 Safety and effectiveness of Fluzone High-Dose in persons <65 years of age have not been  
2 established.

3

#### 4 **8.5 Geriatric Use**

5 Safety and immunogenicity of Fluzone High-Dose have been evaluated in adults 65 years of age  
6 and older. [See *Adverse Reactions (6.1)* and *Clinical Studies (14)*]

7

### 8 **11 DESCRIPTION**

9 Fluzone High-Dose (Influenza Virus Vaccine) for intramuscular injection is an inactivated  
10 influenza virus vaccine, prepared from influenza viruses propagated in embryonated chicken eggs.  
11 The virus-containing allantoic fluid is harvested and inactivated with formaldehyde. Influenza  
12 virus is concentrated and purified in a linear sucrose density gradient solution using a continuous  
13 flow centrifuge. The virus is then chemically disrupted using a non-ionic surfactant, Octylphenol  
14 Ethoxylate (Triton® X-100), producing a “split virus”. The split virus is further purified and then  
15 suspended in sodium phosphate-buffered isotonic sodium chloride solution. The Fluzone High-  
16 Dose process uses an additional concentration factor after the ultrafiltration step in order to obtain  
17 a higher hemagglutinin (HA) antigen concentration.

18

19 Fluzone High-Dose suspension for injection is clear and slightly opalescent in color.

20

21 Neither antibiotics nor preservative are used in the manufacture of Fluzone High-Dose.

22

23 The Fluzone High-Dose prefilled syringe presentation does not contain latex.

1

2 Fluzone High-Dose is standardized according to United States Public Health Service requirements  
3 and is formulated to contain HA of each of the following three influenza strains recommended for  
4 the 2012-2013 influenza season: A/California/07/2009 NYMC X-179A (H1N1),  
5 A/Victoria/361/2011 IVR-165 (H3N2) and B/Texas/6/2011 (a B/Wisconsin/1/2010-like virus).

6 The amounts of HA and other ingredients per dose of vaccine are listed in [Table 2](#).

7 **Table 2: Fluzone High-Dose Ingredients**

	Quantity (per dose)
Ingredient	Fluzone High-Dose 0.5 mL Dose
<b>Active Substance: Split influenza virus, inactivated strains<sup>a</sup>:</b>	180 mcg HA total
A (H1N1)	60 mcg HA
A (H3N2)	60 mcg HA
B	60 mcg HA
<b>Other:</b>	
Sodium phosphate-buffered isotonic sodium chloride solution	QS <sup>b</sup> to appropriate volume
Formaldehyde	≤100 mcg
Octylphenol Ethoxylate	≤250 mcg
Gelatin	None
<b>Preservative</b>	None

8 <sup>a</sup>per United States Public Health Service (USPHS) requirement.

9 <sup>b</sup>Quantity Sufficient.

10

1 **12 CLINICAL PHARMACOLOGY**

2 **12.1 Mechanism of Action**

3 Influenza illness and its complications follow infection with influenza viruses. Global surveillance  
4 of influenza identifies yearly antigenic variants. For example, since 1977, antigenic variants of  
5 influenza A (H1N1 and H3N2) viruses and influenza B viruses have been in global circulation.

6 Specific levels of hemagglutination inhibition (HI) antibody titer post-vaccination with  
7 inactivated influenza virus vaccines have not been correlated with protection from influenza virus  
8 infection. In some human studies, antibody titers  $\geq 1:40$  have been associated with protection from  
9 influenza illness in up to 50% of subjects. (2) (3)

10  
11 Antibodies against one influenza virus type or subtype confer limited or no protection against  
12 another. Furthermore, antibodies to one antigenic variant of influenza virus might not protect  
13 against a new antigenic variant of the same type or subtype. Frequent development of antigenic  
14 variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the  
15 usual change of one or more new strains in each year's influenza vaccine. Therefore, influenza  
16 vaccines are standardized to contain the hemagglutinins of influenza virus strains representing the  
17 influenza viruses likely to be circulating in the US in the upcoming winter.

18  
19 Annual vaccination with the current vaccine is recommended because immunity during the year  
20 after vaccination declines, and because circulating strains of influenza virus change from year to  
21 year.

22  
23 **13 NON-CLINICAL TOXICOLOGY**

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### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Fluzone High-Dose has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

## 14 CLINICAL STUDIES

### 14.1 Immunogenicity of Fluzone High-Dose in Geriatric

#### Adults

Adults 65 years of age and older were randomized to receive either Fluzone High-Dose or Fluzone (year 2006-2007 formulation) in a multi-center, double-blind trial conducted in the US. For immunogenicity analyses, 2,576 participants were randomized to Fluzone High-Dose and 1,275 participants were randomized to Fluzone. Females accounted for 51.3% of participants in the Fluzone High-Dose group and 54.7% of participants in the Fluzone group. In both groups, the mean age was 72.9 years (ranged from 65 through 97 years in the Fluzone High-Dose group and 65 through 94 years in the Fluzone group); 35% of participants in the Fluzone High-Dose group and 36% of participants in the Fluzone group were 75 years of age or older. Most participants in the Fluzone High-Dose and Fluzone groups, respectively, were Caucasian (91.7% and 92.9%), followed by Hispanic (4.8% and 3.7%), and Black (2.7% and 2.7%).

The primary endpoints of the study were HI GMTs and seroconversion rates 28 days after vaccination. Pre-specified statistical superiority criteria required that the lower limit (LL) of the 2-sided 95% CI of the GMT ratio (Fluzone High-Dose/Fluzone) be greater than 1.50 for at least two of the strains, and if one strain failed, non-inferiority of that strain must be demonstrated (LL>0.67), and that the lower limit of the 2-sided 95% CI of the seroconversion rate difference

1 (Fluzone High-Dose minus Fluzone) be greater than 10% for at least two of the strains, and if one  
2 strain failed, non-inferiority of that strain must be demonstrated (LL>-10%). As shown in [Table 3](#),  
3 statistically superior HI GMTs and seroconversion rates after vaccination with Fluzone High-  
4 Dose compared to Fluzone were demonstrated for influenza A subtypes, A (H1N1) and A  
5 (H3N2), but not for influenza type B. For strain B, non-inferiority of Fluzone High-Dose  
6 compared to Fluzone was demonstrated for both the HI GMTs and seroconversion rates. There are  
7 no data demonstrating clinically relevant prevention of culture-confirmed influenza or its  
8 complications after vaccination with Fluzone High-Dose compared to Fluzone in individuals 65  
9 years of age and older.

10

1 **Table 3: Post-Vaccination HI Antibody GMTs and Seroconversion Rates and Analyses of**  
2 **Superiority of Fluzone High-Dose Relative to Fluzone, Adults 65 Years of Age and Older**

Influenza Strain	GMT		GMT Ratio	Seroconversion % <sup>a</sup>		Difference	Met Both Pre-defined Superiority Criteria <sup>c</sup>
	Fluzone High-Dose N <sup>b</sup> =2542-2544	Fluzone N <sup>b</sup> =1252	Fluzone High-Dose over Fluzone (95% CI)	Fluzone High-Dose N <sup>b</sup> =2529-2531	Fluzone N <sup>b</sup> =1248-1249	Fluzone High-Dose minus Fluzone (95% CI)	
<b>A (H1N1)</b>	115.8	67.3	1.7 (1.6; 1.8)	48.6	23.1	25.4 (22.4; 28.5)	Yes
<b>A (H3N2)</b>	608.9	332.5	1.8 (1.7; 2.0)	69.1	50.7	18.4 (15.1; 21.7)	Yes
<b>B</b>	69.1	52.3	1.3 (1.2; 1.4)	41.8	29.9	11.8 (8.6; 15.0)	No

3 <sup>a</sup>Seroconversion: Paired samples with pre-vaccination HI titer <1:10 and post-vaccination (day 28) titer ≥1:40 or a  
4 minimum 4-fold increase for participants with pre-vaccination titer ≥1:10.

5 <sup>b</sup>N is the number of vaccinated subjects with available data for the immunologic endpoint listed.

6 <sup>c</sup>Predefined superiority criterion for seroconversion: the lower limit of the two-sided 95% CI of the difference of the  
7 seroconversion rates (Fluzone High-Dose minus Fluzone) is >10%. Predefined superiority criterion for the GMT  
8 ratio: the lower limit of the 95% CI for the GMT ratio (Fluzone High-Dose divided by Fluzone) is >1.5.

9

1    **15 REFERENCES**

2

3    1    Lasky T, Terracciano GJ, Magder L, et al. The Guillain-Barre' syndrome and the 1992-1993  
4        and 1993-1994 influenza vaccines. *N Engl J Med* 1998;339(25):1797-802.

5    2    Hannoun C, Megas F, Piercy J. Immunogenicity and protective efficacy of influenza  
6        vaccination. *Virus Res* 2004;103:133-138.

7    3    Hobson D, Curry RL, Beare AS, Ward-Gardner A. The role of serum haemagglutination-  
8        inhibiting antibody in protection against challenge infection with influenza A2 and B  
9        viruses. *J Hyg Camb* 1972;767-777.

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## **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **16.1 How Supplied**

Single-dose, prefilled syringe, without needle, 0.5 mL, package of 10 (does not contain latex)  
NDC 49281-391-65.

### **16.2 Storage and Handling**

Store Fluzone High-Dose refrigerated at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Discard if  
vaccine has been frozen.

Do not use after the expiration date shown on the label.

## **17 PATIENT COUNSELING INFORMATION**

See FDA-approved patient labeling (Patient Information).

- Inform the patient or caregiver that Fluzone High-Dose contains killed viruses and cannot cause influenza.
- Fluzone High-Dose stimulates the immune system to produce antibodies that help protect against influenza, but does not prevent other respiratory infections.
- Annual influenza vaccination is recommended.
- Instruct vaccine recipients and caregivers to report adverse reactions to their healthcare provider and/or to Vaccine Adverse Event Reporting System (VAERS).

Fluzone is a registered trademark of Sanofi Pasteur Inc.

1

2 Manufactured by:

3 **Sanofi Pasteur Inc.**

4 Swiftwater PA 18370 USA

6218

5

6

1 **Patient Information Sheet**  
2 **Fluzone® High-Dose**  
3 **Influenza Virus Vaccine**  
4

5 Please read this information sheet before getting Fluzone® High-Dose vaccine. This summary is  
6 not intended to take the place of talking with your healthcare provider. If you have questions or  
7 would like more information, please talk with your healthcare provider.  
8  
9

10 **What is Fluzone High-Dose vaccine?**

11 Fluzone High-Dose is a vaccine that helps protect against influenza illness (flu).

12 Fluzone High-Dose vaccine is for people 65 years of age and older.

13 Vaccination with Fluzone High-Dose vaccine may not protect all people who receive the vaccine.  
14  
15

16 **Who should not get Fluzone High-Dose vaccine?**

17 You should not get Fluzone High-Dose vaccine if you:

- 18 • ever had a severe allergic reaction to eggs or egg products.  
19 • ever had a severe allergic reaction after getting any flu shot.  
20 • are younger than 65 years of age.  
21

22 Tell your healthcare provider if you have or have had:

- 23 • Guillain-Barré syndrome (severe muscle weakness) after getting a flu shot.  
24 • problems with your immune system as the immune response may be diminished.  
25  
26

27 **How is Fluzone High-Dose vaccine given?**

28 Fluzone High-Dose vaccine is a shot given into the muscle of the arm.  
29

1                   **What are the possible side effects of Fluzone High-Dose vaccine?**

2   The most common side effects of Fluzone High-Dose vaccine are:

- 3   • soreness, pain and swelling, redness where you got the shot  
4   • muscle ache  
5   • tiredness  
6   • headache

7   These are not all of the possible side effects of Fluzone High-Dose vaccine. You can ask your  
8   healthcare provider for a list of other side effects that is available to healthcare professionals.

9

10   Call your healthcare provider for advice about any side effects that concern you. You may report  
11   side effects to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or  
12   <http://vaers.hhs.gov>.

13

14

15                   **What are the ingredients in Fluzone High-Dose vaccine?**

16   Fluzone High-Dose vaccine contains 3 killed flu virus strains.

17   Inactive ingredients include formaldehyde and octylphenol ethoxylate.

18

19   Manufactured by: Sanofi Pasteur Inc.

20   Swiftwater, PA 18370 USA